FDA "White Paper"
(Draft)

INTRODUCTION

Smoking has been a popular practice since long before the existence of any scientific knowledge about the components of tobacco. Until recently, U.S. government efforts to stamp out smoking have been limited by its popularity and by respect for the strong American presumption in favor of allowing adults to make their own decisions in matters of behavior. Now, though, Food and Drug Commissioner David Kessler is challenging the idea that Americans are competent to make their own choices in this area. He is doing so in order to bring tobacco under his regulatory jurisdiction.

In a letter released to the public on February 25, 1994, Commissioner Kessler raised the possibility that the agency may be able to regulate cigarettes under the "drug" provision of the federal Food, Drug, and Cosmetic Act. A month later, in testimony to Congress, he explained his reasoning: There is new and mounting evidence, he said, that the nicotine in cigarettes is addictive. Further, his argument went, cigarette makers add and manipulate nicotine-- or, as some critics put it, "spike" cigarettes-- to create and sustain addiction among smokers. In Kessler's view, smokers can not be allowed to make up their own minds about cigarettes because their addiction, rather than their free will, governs their decisions. Furthermore, if tobacco makers actually intend to foster this addiction, their products can be classified as drugs and regulated for the protection of health and safety.

We think the FDA theory wrong on both counts. We further contend that the regulatory burdens entailed in an attempt to regulate and perhaps prohibit smoking pose significant threats to health and safety in this country. Finally, we think that prohibition, the logical end of Commissioner Kessler's efforts, will not only offend the idea of individual choice but bring vast, concrete safety and law enforcement problems in its wake.

Part One of this paper will consider the FDA's rationale for claiming jurisdiction over cigarettes. It will ask whether nicotine is a true addictive drug and whether manufacturers raise or manipulate nicotine levels in cigarettes.

Part Two will ask whether the FDA is capable of doing the job of cigarette regulation responsibly, whether a regulatory bureaucracy is the proper place in which to make basic decisions about smoking, and

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whether the prohibition of cigarettes can be accomplished without unacceptable consequences.

PART ONE: THE FDA'S RATIONALE

I. The Question of Jurisdiction

Under existing law, the Food and Drug Administration may regulate products as drugs only if they are "intended for use in the treatment or prevention of disease... or are intended to affect the structure or any function of the body." In other words, a substance can be classified as a drug only if its manufacturer intends that it be used as a drug. And only if it is classified as a drug can the FDA assert jurisdiction.

The statute is based squarely and unambiguously on the intended use of a product, as revealed in communications like advertising and promotional materials. Since the passage of the original Food and Drug Act, the FDA has abided by this standard with regard to tobacco. The agency has asserted jurisdiction over tobacco products as drugs only when a manufacturer has made express promotional claims urging that a product be used as a drug. Because the major cigarette companies' advertisements and promotional materials make no such health claims about their products, the FDA has never asserted jurisdiction over their cigarettes. In 1977, an anti-smoking group called Action on Smoking and Health (ASH) petitioned the FDA to regulate cigarettes on the ground that nicotine "affects the structure or function of the human body." The agency rejected this argument, finding no evidence that manufacturers intended cigarettes to have such effects. In denying the ASH petition, the FDA summarized, "The interpretation of the Act by the FDA consistently has been that cigarettes are not a drug unless health claims are made by vendors."

ASH appealed the decision to the courts, where the FDA argued in 1979 that "[i]n the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor."

The FDA prevailed in the case.

In 1980 the FDA denied another ASH petition, this one claiming that filter cigarettes, designed to reduce tar and nicotine levels, should be

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regulated as drugs because they were sold with the intent of mitigating alleged smoking-related diseases. The FDA rejected this argument, stating, "[R]epresentations in cigarette labeling or advertising... as to the absolute or relative quantity of hazardous constituents of cigarette smoke or as to the safety of cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease."

In this way, the agency rejected the attempt to impute to cigarette manufacturers a motive different from the one that they themselves claimed and evinced.

The courts have recognized that in theory, a product can be called a drug even without manufacturer intent if consumers use it almost exclusively for drug-like purposes. But the courts have never found any product to be a drug under this theory. Therefore when Commissioner Kessler claimed this year that the FDA can assert jurisdiction over cigarettes, he not only showed a marked disregard for the agency's settled doctrine but took upon himself a heavy burden: In order to gain jurisdiction, he must show that the product is meant to be used as a drug.

Recognizing this burden, Commissioner Kessler has emphasized his "new" circumstantial evidence that manufacturers do in fact intend for cigarettes to be used as a drug. In his February 25 letter, Commissioner Kessler stated, "[The] possible inference that cigarette vendors intend cigarettes to achieve drug effects in some smokers is based on mounting evidence that: 1) the nicotine ingredient in cigarettes is a powerfully addictive agent and 2) cigarette vendors control the level of nicotine that satisfies this addiction."

II. Addictions, Cravings, Dependencies, Habits

Because of the clear requirements of the law, the FDA now seeks to show, as the first step in its argument, that cigarette smoking is clearly addictive and thus deprives smokers of their capacity for free choice. But smoking is called "addictive" today largely because the concept of addiction has expanded over the past 30 years to include everything from the agonizing physical symptoms of withdrawing from heroin to our fascination with video games. The term "addiction" has been employed as an expanding umbrella to cover all such habits precisely because the word carries with it the image of the physically enslaved, personality-distorted, anti-social junkie.

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In the 1964 Surgeon General's Advisory Committee's report on smoking and health, the Surgeon General employed the term "addiction" in a fairly specific way:

> Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include: an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; a tendency to increase the dose; a psychic (psychological) and general physical dependence on the effect of the drug; a detrimental effect on the individual and on society.

The elements of this definition are those that most of us still think of when we picture a drug addict. Applying the definition, the Surgeon General classified smoking as not an "addiction" but a "habit."

By 1980, the concept of addiction had grown more nebulous-- so much so, in fact, that the American Psychiatric Association, in the third edition of its Diagnostic and Statistical Manual of Mental Disorders, dropped the term "drug addiction" and has continued to avoid its use. In 1987, though, another Surgeon General's Report on Nicotine Addiction appeared. It introduced a broader, less precise definition of addiction. The report set forth different criteria for identifying an addictive substance: (1) that highly controlled or compulsive patterns of drug taking occur; (2) that a psychoactive mood-altering drug is ingested through the use of the substance and is involved in the resulting patterns of behavior; and (3) that the drug is capable of functioning as a reinforcer that can directly strengthen behavior leading to further drug ingestion.

By this considerably more expansive definition, the Surgeon General classified nicotine as an "addictive substance." He could have similarly categorized the caffeine in coffee, cola, and chocolate or the relaxing L-tryptophane in the nightly glass of warm milk.

The term "addiction" is now used even more broadly by health officials and others. Psychologists and sociologists have applied the term to activities as diverse as TV-watching, gambling, shopping, exercise, and sex, despite the fact that such pastimes involve no drug use at all. Jerome Jaffe, a well known medical researcher and writer on the subject of addiction, has summed up the current state of affairs by calling his field "a semantic disaster area." He has expressed concern "that all of [our] efforts at diagnosis in this area will be seen as self-serving maneuvers designed to medicalize undesirable behavior."

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In light of the current confusion, much of it self-serving, it is appropriate to list here some concrete respects in which the nicotine smoked in cigarettes differs from the classic "hard drugs" like heroin and cocaine, whose image anti-smoking activists call to the public mind when they invoke the term "addiction."

a. *intoxication*: Nicotine, like many substances and events, is psychoactive in the broad sense of that term. But not every psychoactive substance is an intoxicant, with the characteristic ability to make dramatic changes in a user's mood, perception, or functioning. Substances like heroin, or even the more socially acceptable alcohol, are well known as intoxicants that seriously impair functioning and change not only moods and perceptions but entire personalities.

Nicotine is not an intoxicant. It does not interfere with an individual's thinking or acting. A smoker can drive a car competently, fly a plane, or engage in other daily activities regardless of the presence of nicotine in his or her bloodstream.

b. *tolerance*: Classic addictive substances induce a phenomenon known as tolerance: a user's need to take ever-increasing doses to achieve the level of intoxication once experienced at lower doses. With hard drugs, increasing tolerance may even lead users to increase doses up to a fatal level. With cigarettes, by contrast, smokers arrive at a certain number of cigarettes per day, and this number remains stable for years.

Commissioner Kessler has suggested, consistent with his addiction theory, that "if you lower the dose of nicotine just a little" in a cigarette, "people may end up smoking more cigarettes." Yet there are data on this question, and they suggest a different model of smoker behavior. When smokers switch to lower-nicotine cigarettes, they do not increase their smoking by the number of cigarettes it would take to achieve the high previous total level of nicotine intake. The smoker of an "ultra-low" cigarette delivering 0.1 mg of nicotine would have to smoke 15 to 20 times as many cigarettes to take in the nicotine found in a single medium-yield filter cigarette; there is no evidence that such behavior occurs.

While nicotine levels have been reduced dramatically over the past decades, the average number of cigarettes consumed by an individual

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smoker has not increased but has declined slightly. Users of low-yield brands smoke the same number of cigarettes as do users of high-yield brands.

None of this behavior is consistent with the familiar model of increasing hard-drug tolerance.

c. *withdrawal*: Classic withdrawal is the extremely painful physical reaction that occurs when an individual stops taking certain substances, especially depressants like opiates and barbiturates. Symptoms range from seizures to hallucinations. Barbiturate withdrawal, for instance, is marked by hallucinations, tremors, and vomiting; it is potentially fatal and should be treated on an in-patient basis.

Even long-term, heavy smokers can quit without serious physical manifestations. Quitting may lead to irritability, but this type of discomfort is simply not the same as a drug withdrawal syndrome. Quitting smoking has no direct medical consequences, and smokers require neither hospitalization nor sustained medical attention while quitting.

Physiologically, in fact, quitting smoking is more comparable to the way individuals feel when they give up an activity like drinking coffee. Commissioner Kessler, to support the theory of nicotine addiction, cites poll data that show three out of four smokers claiming to be addicted to cigarettes. Yet these data are suspect: Because smoking is now viewed by many as antisocial behavior, a smoker being polled has an incentive to claim that he or she is not really responsible for this behavior.

Making the data even less useful is the fact that in the very same poll, seven out of ten smokers said they could quit smoking if they decided to do so.

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So if patterns of cigarette use can not be understood in the same terms as those we properly use for addiction, how should we understand them? If smokers are not "addicts," why do they smoke?

We suggest that the proper comparison is with other activities, with or without some psychoactive component, that may be considered risky by the medical community but provide a complex mix of pleasures and

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satisfactions. Some people like the look and feel of a pack of cigarettes or the smell of tobacco. Some like to hold and fiddle with a cigarette. Others like the taste and aroma of the tobacco and the sight of the smoke. Still others find smoking a distraction that relieves the anxiety attendant on high-stress tasks.

These motivations are more complex than just the desire to obtain nicotine. Indeed, only by acknowledging this complexity can one account for the fact that simple nicotine replacement therapies for smokers have had such a low rate of success.

Nicotine gum, for one, is sold as a prescription smoking-cessation aid and has been marketed for several years. If, as proponents of the "addiction theory" maintain, people smoke only to get nicotine, then nicotine gum should satisfy a smoker's desire for a cigarette. The gum should be interchangeable with smoking; quitting should be simply a matter of switching from cigarettes to gum.

In fact, the nicotine gum does not erase the desire to smoke and has not been shown to be an effective smoking-cessation aid. Indeed, it is not FDA-approved for this purpose except in conjunction with psychological counseling.

In the same way, the successor to nicotine gum, the modern nicotine patch, has not had marked success in promoting cessation. Even under the most favorable interpretations, only a quarter of users of the nicotine patch will find that its steady infusion of nicotine keeps them away from smoking.

Clearly, then, the critical element in quitting is not physical addiction. The 1987 Surgeon General's report tells us that 90 percent of the more than 40 million former smokers in the United States at that time had quit smoking on their own, without medical or other outside help. These figures would not be possible if the physical compulsion of nicotine had the determinative power that the "addiction" theorists ascribe to it.

III. The Great Manipulators?

The first part of the logic by which the FDA claims jurisdiction over tobacco asserts that nicotine is powerfully addictive. The second part argues that cigarette manufacturers manipulate the levels of nicotine in their products so as to create and sustain the addiction.

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This contention, like the addiction theory, is simply wrong.

By blending types of tobacco for various taste experiences, manufacturers do make different brands with different tar yields-- and thus different levels of nicotine, which follow tar levels. But they do not add to the nicotine that occurs naturally in tobacco. Indeed, in response to consumer demand nicotine levels in cigarettes have steadily declined over the past 40 years. Sales-weighted tar and nicotine levels have decreased 60 to 70 percent since 1957.

a. *how it's done*: This decline in nicotine levels has not been a chance occurrence. American consumers have expressed a preference for lower-yield cigarettes, and cigarette companies responded with a variety of techniques for reducing nicotine and tar levels. In today's cigarette brands, these techniques reduce the yield of nicotine and other constituent substances by as much as 99 percent when compared with a standard, unfiltered cigarette made of tobacco and paper alone. Cigarette makers are now provide smokers with a range of products featuring yields as low as one mg of tar and 0.1 mg of nicotine.

(1) filtration: The most important development in cigarette manufacturing during the past four decades has been the use of increasingly efficient filters, which substantially reduce yields of many smoke components, including tar and nicotine. This filter technology has been widely publicized in scientific journals and the popular press, as well as in advertising by the companies themselves.

(2) ventilation: A second important technique for reducing yields of many smoke components, including tar and nicotine, is ventilation, which draws room air in through the sides of the cigarette filter. When this process was first developed in the late 1960s, it used large, visible holes. As the technology became more sophisticated, lasers were used to create smaller, more uniform, nearly invisible holes arranged in bands on the filter-tipping paper. The location of these holes makes it difficult for a smoker to cover them with lips or fingers. The more even distribution of these holes reduces the possibility that they will be significantly blocked in the normal smoking process.

(3) expanded tobacco: A third technique for reducing tar and nicotine delivery levels is the use of expanded tobacco. Through a process patented by Philip Morris and now licensed to other manufacturers, tobacco is "puffed" in much the same manner as "puffed rice" cereal. As a result, a given amount of tobacco will occupy

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a greater volume in the tobacco rod; it will take less tobacco to fill the rod, and available levels of tar and nicotine in the cigarette will be correspondingly reduced.

(4) blended leaf and reconstituted tobacco: The blended leaf process uses stems and small leaf parts, which are blended with water, ammonia, flavors, and humectants. The ammonia acts as a processing aid to release the naturally occurring pectin in tobacco. This pectin becomes a binder for the small tobacco pieces, holding them together to form a sheet. During the sheet-forming process, most of the ammonia is then removed; the sheet is then used in cigarette production. Approximately 25 percent of the nicotine in the tobacco is lost during this process. It is not replaced.

Refined Leaf tobacco is also made from tobacco stems and small leaf parts. In this process, which employs technology owned by Kimberly Clark, the tobacco pieces are crushed and mixed with water in a tank called a pulper. The soluble substances in the tobacco, including nicotine and other flavorants, are separated from the fiber portion, leaving it a tasteless sheet. The solubles are then mixed with other flavors, humectants, and preservatives, and recombined with the tobacco fiber to form a reconstituted tobacco sheet with restored taste.

Though Philip Morris controls the overall soluble content in the final reconstituted sheet, it does not specifically control or even test for the amount of nicotine within this soluble content. We estimate that about 20 percent of the nicotine contained in the tobacco entering the reconstitution process is lost. It is not replaced.

(5) blending: Raw tobacco varies, not only in nicotine content but in many other attributes, as a result of variations in weather and growing conditions. But in order to sell consistent products and promote brand loyalty, tobacco companies must produce cigarettes with a uniform taste. Therefore the companies blend crops from multiple growing regions, generally covering three years, in order to even out fluctuations. Manufacturers select blends to yield the taste characteristics of particular brands.

This process is not designed to addict smokers. It does not add nicotine to what occurs naturally in tobacco.

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Critics, including the FDA, allege that cigarette manufacturers add nicotine to cigarettes in order to "keep smokers addicted." These charges are false: No manufacturer, in processing or blending tobaccos or in making cigarettes, adds nicotine. All nicotine in a cigarette is naturally present in the tobacco. Indeed, cigarette makers have developed a manufacturing process markedly ill suited to the job of monitoring or controlling nicotine levels in their products.

Philip Morris maintains over 400 quality control checkpoints in the manufacturing process. The close monitoring is necessary: Manufacturers must deliver cigarettes that are consistent and uniform in taste in order to meet consumer demand.

Yet the company measures nicotine at only two points-- at the stemmery, where tobacco leaves are first separated from the stem, and one to three years later, after those leaves have already left the manufacturing process and been converted into finished cigarettes.

The absence of specific control for nicotine is known to the FDA and to the General Accounting Office, whose representatives have visited Philip Morris and watched the process in detail. Unfortunately, this awareness has not prevented the Commission from charging the companies with things that are not true.

b. *the low-nicotine "myth" myth*: In one charge against the manufacturers, Commissioner Kessler testified to Congress that today's low-yield cigarettes are a "myth." He pointed to the fact that some low-nicotine cigarettes contain tobacco with a relatively high nicotine concentration by weight, and to the fact that some low-yield cigarettes have a relatively high ratio of nicotine to tar.

These arguments reveal either bad faith or ignorance about the process of making cigarettes.

It is true that some low-yield cigarettes contain slightly higher nicotine concentrations in their tobacco than do some full-flavored cigarettes. Here is how this high concentration occurs: Manufacturers sometimes greatly reduce the tar in a cigarette brand. They may reduce the amount of Oriental tobacco in their mix, because Oriental tobacco is relatively high in tar.

Tar content correlates roughly with taste. For example, when tar is reduced by as much as 92 percent, taste is correspondingly reduced. To compensate partially for this "lighter taste," manufacturers may use

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less in the way of reconstituted tobacco products, which are not as flavorful as other types of tobacco.

Oriental tobacco, though it is high in tar, is low in nicotine. Reconstituted tobacco products are low in nicotine. Removing such low-nicotine tobaccos from the mix can have the net result of producing a somewhat higher concentration of nicotine in the filler tobacco of the cigarette.

On the other hand, in order to reduce tar, low-yield cigarettes use a large percentage of expanded tobacco. This means each of them contains less tobacco. Even though the concentration of nicotine in the tobacco is somewhat higher, the absolute amount of nicotine in the cigarette is lower, because there is less tobacco to burn.

In the end, the concentration of nicotine in the tobacco does not significantly affect the nicotine actually delivered in the smoke. The combination of lower tobacco weight per cigarette, higher filtration efficiency, and ventilation reduces the nicotine delivered in the smoke of these cigarettes by as much as 99 percent.

The increasingly effective filtration and ventilation systems also provide the answer to Commissioner Kessler's charge of high nicotine-to-tar ratios in low-nicotine cigarettes. Those ratios occur because of the physical properties of tar versus nicotine: The combination of filtration and ventilation is slightly more efficient at removing tar than it is at removing nicotine. But the net effect is a reduction in both the tar and the nicotine.

So the changing ratios, which the FDA presents as evidence of manufacturer manipulation, do not in fact show such manipulation.

c. *the "misleading test" charge*: Commissioner Kessler has also denied the existence of low-nicotine cigarettes by claiming that the industry uses a misleading procedure to test for nicotine levels. In fact, this methodology, used for the past 25 years, was developed by the U.S. Department of Agriculture. Following discussion and public hearings, the Federal Trade Commission itself adopted the method to use in its own testing. Since 1980, the tests have been performed, according to the same methodology, by the Tobacco Institute Testing Laboratory at the request of the FTC.

All tests are conducted on finished cigarettes, identical to cigarettes smoked by consumers, after all manufacturing processes have been

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completed. The tests can not measure all variations based on differences in individual smoking styles, just as the Environmental Protection Agency's gas mileage tests can not measure variations caused by different driving styles. But the FTC-method tests establish different brands' relative nicotine yields on a consistent basis, just as EPA's tests establish relative gas mileage among auto makes.

The FTC's information on the nicotine delivery of commercial cigarettes is measured to the tenth of a milligram and is disclosed in public releases by the FTC and in every cigarette advertisement.

d. *the "spiking" charge*: In another version of the "manipulation" charge, critics have said that manufacturers are "spiking" cigarettes with nicotine to sustain addiction by means such as adding tobacco extracts and adding nicotine in the form of nicotine sulfate to the alcohol used during the manufacturing process.

The fact is that cigarette makers, like many makers of foods and beverages, use alcohol in the manufacturing process as a solvent and carrier of flavors, because certain flavors are not water-soluble. An agent is added to the alcohol in order to make it bitter and therefore undrinkable. The formula for this "denaturing" is set by the Bureau of Alcohol, Tobacco and Firearms and published in the Code of Federal Regulations. It prescribes that the alcohol be denatured with nicotine sulfate, since nicotine occurs naturally in tobacco.

The amount of nicotine in the denatured alcohol is so small that it can not even be measured in cigarette smoke. It has no measurable effect on nicotine delivery in cigarettes.

In the same way, the nicotine in tobacco extracts has no measurable impact on nicotine levels in finished cigarettes or cigarette smoke. Philip Morris does not use these extracts now. But even when these substances are used in the highest concentrations at which Philip Morris ever used them, they increase the amount of nicotine in a cigarette only by some .009 percent, far less than the natural variation in the raw tobacco itself or the weight variation from cigarette to cigarette.

e. *the false charge on patents*: At the March 25 Congressional hearing, the FDA spent a great deal of time trying to support the charge that tobacco companies use "secret" patented processes, whose discovery is a recent "revelation," to increase or maintain nicotine levels in cigarettes. The charge is false.

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The patents identified by the FDA are not secret. All the patents, some dating back 30 years, are on public file in the U.S. Patent and Trademark Office, in conformity with this country's patent laws. The papers reveal all the data-- not only the patents themselves but their detailed application-- relating to the inventions and discoveries involved.

Some of the patents are for processes meant not to increase the nicotine in tobacco but to extract or remove the nicotine. In fact, out of the group of patents referred to by the FDA, the only patents that have ever been used are those that reduce-- and, in one case, virtually eliminate-- nicotine from tobacco.

Three of the patents, very old ones, theoretically discuss the addition of nicotine to the filter or rod of a cigarette. But these early patents were never practiced. In the same way, company chemists have from time to time developed chemical structures analogous to that of nicotine in an effort to see whether they could replicate some of its properties while eliminating others. None of these analogs has proved useful, and none has ever been used.

The existence of these patents is not evidence that it was ever intended for them to be practiced. Companies routinely conduct basic research with no necessary commercial implications, and they patent new chemical structures and processes even when there has been absolutely no demonstration or even testing of whether the structures can be used. This sequence of events is common, in the tobacco industry and in industry as a whole, and is consistent with the patent law's purpose of promoting maximum scientific invention.

Commissioner Kessler has admitted that he has no evidence of companies' actually using any patented processes to increase or maintain nicotine delivery levels in cigarettes. "It is prudent," he has put it, "to keep in mind that patents do not necessarily tell us what processes are currently being used in manufacturing cigarettes." The same logic should have suggested that the patents not be used as a polemical weapon in the first place.

f. *affirmative action*: When all the specific charges are rebutted, critics of the cigarette manufacturers retreat to what they think is an unassailable position. They say that because the manufacturing process is capable of taking nicotine out of cigarettes, manufacturers have an obligation to take it all out. Otherwise, in this view, the tobacco

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companies' inaction makes them no better than promoters of addiction.

This attitude pervaded an exchange in the March 25 hearing between Congressman Henry Waxman (D-Calif.) and Commissioner Kessler:

Mr. Waxman: "You've testified that nicotine could be removed from cigarettes. You've also testified it's possible to duplicate the taste of nicotine.

"I realize that you're not ready to make a final decision, but are you aware of any significant, reliable evidence that would support the proposition that the manufacturers leave nicotine in cigarettes for any reason other than addiction?"

Commissioner Kessler: "No."

Commissioner Kessler is wrong; such evidence does exist. Philip Morris, for one, has made a concentrated effort to market a cigarette composed entirely of tobacco from which virtually all nicotine was removed. The introduction of this cigarette was highly publicized. Within the confines of FDA guidelines, the company promoted the fact that the cigarette was composed entirely of tobacco treated through a new denicotinizing process. The company also encouraged the purchase of the new cigarette through substantial promotions over a number of months. In all, Philip Morris spent approximately $300 million to develop and market the brand.

The new cigarette was a flop. There were several reasons: First, it is difficult to launch any new brand of cigarettes. Moreover, several brands with very little nicotine were already on the market, so that consumers did not perceive a still-greater reduction in nicotine as a powerful selling point. However, another major factor in the failure of the denicotinized brand was that the nicotine extraction process altered the taste of the tobacco by removing the nicotine and other flavorants necessarily extracted along with it. Consumers reported that they did not like the resulting taste, which many described as "flat."

Cigarette makers do not have to be promoters of addiction to look at this example and hesitate before trying to take all the nicotine out of their cigarettes.

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PART TWO: CONSEQUENCES OF REGULATION

I. Congress in Control

Congress has repeatedly and explicitly asserted its direct control of policymaking in regard to tobacco. In 1964, after the first Surgeon General's report on smoking, the House Committee on Interstate and Foreign Commerce considered the document's implications. On one matter the committee was clear: "The determination of appropriate remedial action in this area, as recommended by the Surgeon General's Advisory Committee, is a responsibility which should be exercised by Congress after considering all facets of the problem." If policy was to be set, it was to be Congress that did the job.

The next year, Congress made its response by passing the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965. Congress declared that the act's purpose was "to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Congress explicitly permitted the continued marketing of cigarettes but required that information be provided to the public in the form of warning labels and advertising.

The act required that cigarette packages bear a statement advising people of the potential hazards of smoking; at the same time, the act forbade any federal, state, or local authority to require any other warning statement. Through this and other legislation withdrawing state regulatory jurisdiction over cigarettes under various federal statutes, Congress has maintained its policy of close control over the tobacco issue.

The FCLAA, as amended, is part of a coherent policy that Congress has developed towards cigarettes that do not make health claims. This policy consists of five principal elements: (1) that smoking is a matter of individual choice for adults; (2) that smokers and potential smokers should be warned, in the precise words drafted by Congress, about the adverse effects that the federal government believes smoking has on health; (3) that through research and education the government will try to persuade, rather than coerce, smokers to quit; (4) that manufacturers should disclose information on cigarette additives so that Congress and the public can be alerted to any additives presenting undue risks; and (5) that government should encourage the development of cigarettes that yield lower amounts of the compounds involved in the smoking-and-health issue.

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In accordance with this policy, federal laws and regulations cover the way tobacco is raised, harvested, packaged, labeled, advertised, and distributed. The federal government taxes tobacco products, supports anti-smoking research, creates incentives for states to fund anti-smoking programs, and sometimes restricts the locations where cigarettes may be smoked. In addition, state and local government have imposed many regulations. They include smoking restrictions in public and work places, prohibitions on sales to minors, and other restrictions on young peoples' access to tobacco.

The specific types of cigarette regulation are numerous:

a. *the FTC*: Pursuant to Congressional mandate, the Federal Trade Commission monitors and regulates unfair or deceptive advertising of tobacco products. It also ensures that the government's prescribed warning messages appear on all cigarette packs and in all advertising, and it enforces the ban against the broadcast advertising of cigarettes. Moreover, the FTC monitors testing to determine the levels of tar and nicotine in each brand of cigarette. The agency has the authority to publish this information, and it requires information about tar and nicotine levels to appear in all cigarette advertising.

b. *HHS*: Also pursuant to Congressional mandate, the Department of Health and Human Services, of which the FDA is a part, requires cigarette manufacturers to submit annually a list of all ingredients added to tobacco. The Department evaluates the health effects of the listed ingredients and is authorized to inform Congress and the public of its findings. In a number of block grant programs that HHS supervises and implements, the Department provides funds for smoking cessation programs or, as a condition for receiving the money, requires recipient states to prohibit cigarette sales to minors.

c. *BATF*: Under another Congressional mandate, the Bureau of Alcohol, Tobacco and Firearms collects cigarette excise taxes and enforces penalties for nonpayment. BATF also requires disclosure of various data on cigarette cartons and packs, regulates types of processing, and requires companies to report annually on their use.

d. *USDA*: Pursuant to additional Congressional mandates, the Department of Agriculture regulates tobacco as a crop. It grades tobacco before auction, inspects imported tobacco, and, in conjunction with the Environmental Protection Agency, regulates the use of pesticides in tobacco farming. USDA also requires manufacturers to maintain

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records on all finished cigarettes, cigarette-ready tobacco, and exported tobacco products.

e. *EPA*: Along with USDA, the Environmental Protection Agency regulates the use of pesticide in tobacco farming. In addition, at the request of Congress, the EPA issued a December 1992 report detailing the allegedly negative respiratory health effects of passive tobacco smoke.

f. *OSHA*: After the Congressionally mandated EPA report, the Occupational Safety and Health Administration issued a notice of proposed rulemaking in early April, 1994, that would require all employers under OSHA jurisdiction to develop and implement written indoor air quality compliance plans.

g. *CPSC*: At the request of Congress, the Consumer Product Safety Commission issued a report in 1993 on cigarette ignition propensity.

h. *Customs*: The U.S. Customs Service regulates the way in which cigarettes are packaged for importation into the United States.

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These programs warn smokers and potential smokers of possible hazards, discourage smoking through incentives and education, and insure that the public receives all the relevant information about tobacco products. Present government policy balances these programs with a recognition that adults must ultimately make their own free choices and that coercion in this area is not acceptable. Finally, the policy envisions consumer demand prompting cigarette makers to address the smoking-and-health issue through new products and technologies.

This is, in sum, a very American equilibrium.

II. Prohibition

a. the Roaring Nineties: In his February 25 letter, Commissioner Kessler stated that the FDA's gaining jurisdiction over tobacco products "could mean, ultimately, removal from the market of tobacco products containing nicotine at levels that cause or satisfy addiction." Commissioner Kessler continued the scenario: "Only those tobacco products from which the nicotine had been removed or, possibly,

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tobacco products approved by the FDA and labeled for nicotine-replacement therapy would then remain on the market."

The road to prohibition is not hard to map. First, the FDA would declare the nicotine in cigarettes a drug when the nicotine is present at levels sufficient to cause FDA-defined addiction. The agency would then assert jurisdiction over cigarettes on the grounds that they are drug delivery systems. Cigarettes containing the "addictive" levels of nicotine would be considered "new drugs" under the law, because they had not been recognized by experts as "safe and effective," as the law requires. After being placed in the new drug category, cigarettes could not be marketed without the prior approval of the FDA.

It is unlikely that the FDA would approve a new drug application for cigarettes because approval would require the agency to conclude that cigarettes are safe and effective. Rep. Mike Synar posed the question at the March 25 hearing: "... [I]*f you do find nicotine to be a drug, is it* probably, based upon the evidence you've presented today and other evidence which is available, going to be impossible for it to be proven that it can be consumed safely...." Commissioner Kessler answered: "...[T]here are those at the Agency, I must tell you, Congressman, who have a hard time believing that an Agency that is charged with making sure that there are safe and effective products on the market would ever find nicotine-containing cigarettes-- for anyone to establish that they are safe and effective."

In theory, the FDA could allow marketing of cigarettes containing levels of nicotine that the agency says do not cause addiction. However, we have seen that Commissioner Kessler considers low-nicotine cigarettes a "myth." His position strongly suggests that the FDA does not intend to distinguish between high-nicotine and low-nicotine cigarettes in making its regulatory decisions about tobacco.

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As Commissioner Kessler has observed, the FDA's regulation of cigarettes as drugs "could have dramatic effects on our society" and "raises societal issues of great complexity and magnitude." The most probable and important of these social consequences is the emergence of a black market.

The FDA may ultimately succeed in virtually eliminating the availability of commercially manufactured cigarettes, but the agency will not be able to eliminate consumers' desire to smoke. The result

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will be to make criminals of smokers and tobacco farmers. Today's major tobacco companies will be out of the cigarette making business-- even as exporters, since the law precludes the export of unapproved "new drugs" except under very limited circumstances. Thus cigarettes will no longer be manufactured by large, closely supervised companies using advanced patented techniques-- such as filtration, ventilation, and expanded tobacco-- that lower tar and nicotine yields as well as levels of other smoke components. Just as important, smokers will have no information about these yields. Moreover, bootleg cigarettes will contain unknown ingredients. Illicit drugs are now frequently "cut" with substances worse than the drugs themselves; bootleg cigarettes may well carry the same danger.

Distribution of cigarettes, having been declared a crime, will be done by criminals. There is already substantial trafficking in unstamped-- i.e., untaxed-- cigarettes. These traffickers will provide a ready infrastructure for expansion into the bootleg cigarette business. As with the unstamped cigarette, no taxes will be paid.

There is every reason to expect that cigarette prohibition will give organized crime in this country a boost comparable to the one it received from the prohibition of alcohol in the 1920s. Since cigarettes will remain legal in every other country in the world, an FDA ban on U.S. production will simply increase efforts to import them illegally into the United States. The price of the commodity would rise; and, as with so many efforts to improve humankind, the price increases would have a disproportionate impact on low-income smokers.

b. *extending the analogy*: Once the FDA accepts and promulgates its theory of nicotine as an addictive substance and a drug, it is difficult to see how the agency will be able to distinguish the role of nicotine in tobacco from the role of alcohol in alcoholic beverages or of caffeine in coffee, tea, and cola. If the FDA obtains jurisdiction under its new theory of addiction, it will be very easy for activists to make the case that the agency should extend its reach to these other substances as well. Certainly many people drink alcohol not just for the taste but also for its relaxation effect. Indeed, some consume alcohol recognizing that they may-- or even want-- to become intoxicated. Likewise, many people drink caffeinated beverages not only for their taste but also for the stimulant effect.

Under current law, foods may not be regulated simply because they affect the human body. But foods may indeed be regulated as drugs when they are intended for use in treating or preventing withdrawal

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symptoms. People addicted to alcohol or caffeine suffer such symptoms, which are well recognized and documented in the medical literature. It might be said that when these people drink alcohol or cola, they are treating their addictions. By this logic, alcohol and caffeine are drugs, subject to drug regulation.

When arguments are accepted in public discourse, they tend to extend their reach into areas far beyond their original use. Today it may seem absurd to think that beer and cola merit the treatment accorded to hard drugs. But no one should be surprised to hear such talk in the future if nicotine is allowed to set the precedent.

III. The Special Problem of the FDA

Even were the country to decide on a new regime of tobacco regulation, the Food and Drug Administration would be a poor candidate for the job. Commissioner Kessler has stated that the agency does not yet have all information it needs to make final judgments on tobacco; therefore its first regulatory step would be fact-finding. The process would be complicated, since the agency has already put forth, as the basis for its regulatory initiative, assertions that are clearly wrong. To take just one example, the agency has suggested that manufacturers "spike" tobacco to promote addiction; as we have seen, this charge is false.

In the face of agency errors like this one, tobacco manufacturers will defend themselves. The proceedings will be lengthy. If as a result of this process the FDA issues a ruling that allows some cigarettes to remain on the market, the agency will assume a huge new regulatory burden. If the FDA bans cigarettes, it will have to struggle with the equally large burden of anti-black-market enforcement.

* * *

Policymakers should think twice about embarking on this road, because the FDA is widely known as an agency stretched beyond its limits. The situation is not likely to change markedly. Therefore the resources the FDA puts into tobacco regulation will come out of other agency tasks. These other tasks are of extraordinary importance to Americans, and the transfer of resources away from these functions will entail serious losses for the country.

a. *the special relationship*: The FDA is responsible for assuring the safety and effectiveness of medical drugs and devices. It is charged with safeguarding the nation's food supply; it is therefore also obliged to

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oversee animal vaccines and drugs, which often become part of the food supply. As part of this responsibility, the agency bears the burden of managing some of the nation's most frightening crises. When the country becomes alarmed by a product like silicone implants, the FDA must alleviate public anxiety even if this job requires diverting people and funds from the organization's more prosaic tasks.

b. *the regulation explosion*: During the 1980s, Congress simultaneously increased the FDA's statutory mandates and essentially froze its funding. Between 1980 and 1993, Congress passed over 50 new measures enlarging the FDA's responsibilities; 13 such laws were passed in 1990 alone. Many of these statutes required detailed implementing regulations and imposed major new resource burdens on the agency. For example, the Nutrition Labeling and Education Act of 1990 required the agency to devise re-labeling rules for much of the processed food industry. The Safe Medical Devices Act of the same year tripled the number of reports of adverse reactions-- from 26,000 in 1990 to 86,000 in 1992-- with which the agency must deal.

The workload is also increasing because of growth in the size of the FDA's regulated industries, such as food, drugs, medical devices, and biotech. Imports of products under FDA jurisdiction have tripled in the past 20 years, from 500,000 entries in 1971 to 1.5 million in 1990. The number of applications for experimental products rose by 82 percent between 1980 and 1989. Because of continuing technological advances in these industries, the expansion of regulatory duties is likely to accelerate.

Rep. Henry Waxman (D-Calif.) summed up the situation: "During the 1980s, the Food and Drug Administration declined to the point where it was on the verge of not functioning at all."

c. *the chronic incapacity*: Since Commissioner Kessler took office in 1990, he has sought to revitalize the agency. But it is still not effectively doing the basic job it was created to do. These shortcomings are no secret; consumer advocates in Congress have repeatedly taxed the FDA with them. As recently as June 13, 1994, Rep. John Dingell (D-Mich.) stated the problem this way:

> [W]e know full well that Congress cannot provide FDA with the full resources it needs to keep up with its work. Because of this, we must be vigilant not to assign the agency highly resource-intensive obligations that it will find enormously difficult, if not impossible, to fulfill.

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[I]f it were feasible to increase FDA's resources, the Congress should examine closely to what purpose those resources should be put. Should those funds go, for example, to improving the agency's existing seafood regulation program, controlling the entry into the U.S. of contaminated and misbranded foreign products, implementing the Mammography Quality Standards Act, continuing to reduce review times for medical devices and human and animal drugs, or fully implementing congressional requirements related to the safety of medical devices? Or would it be in the best interest either of FDA or the public health to assign the agency's increased resources to an altogether new regulatory activity that, because of its controversial nature, would be tied up in litigation for years and consume enormous agency and other government funds in the process? I am not persuaded that the latter course is best.

Senator John Glenn (D-Ohio) has judged, "We have stretched this Agency and its dedicated employees to the limit, if not beyond."

In 1991 the Edwards committee, a blue-ribbon panel of experts appointed by the Secretary of Health and Human Services, concluded that the FDA was "overextended and underfunded" and recommended that it (1) abandon federal regulation of certain activities, (2) transfer authority over some activities to other, more appropriately equipped federal agencies, and (3) relinquish responsibility for certain functions to state and local governments.

There is good reason for the critics' despair. The FDA suffers from inadequate staffing. Its facilities are outdated and in disrepair. Lack of resources undermines the quality of science performed in FDA laboratories and the credibility of the agency's scientific judgment. This chronic problem has serious consequences. As of 1991, despite the agency's efforts, new drug approvals took an average of 29 months, rather than complying with the 180-day maximum stipulated by law. Not surprisingly, some 80 percent of the drugs approved by the FDA between 1987 and 1989 had already been available-- for an average of six years-- in other nations.

The agency falls short in performing other current duties as well. For instance, seizure of adulterated and misbranded drugs dropped from 539 in 1980 to 183 in 1992, despite an absence of evidence that the underlying problems have abated. In 1991, the FDA sampled only a little more than two percent of imported foods; of the foods sampled, fully 40 percent were rejected because of contamination by bacteria,

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pesticides, insects, or filth, or because of decomposition or labeling deficiencies.

By law, the agency is required to inspect each of 90,000 domestic food and drug manufacturing establishments once every two years. Based on 1991 inspection rates, the actual pace is closer to once every six years. Inspection rates abroad are also substandard: For example, from 1985 to 1989 the agency inspected only 31 of the almost-4000 registered foreign canneries.

There are also extraordinary delays in the agency's rulemaking. According to a February, 1992 GAO report, the average published FDA rule proposal is not promulgated for more than five years. Some rules have taken as long as 20 to 30 years to be fully implemented.

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The crisis will continue and intensify. Some 26 bills now before Congress would expand the FDA's jurisdiction still further. These bills address issues as diverse as the safety of pesticide residues in the food supply, the FDA's role in drug pricing as a component of health care reform, adequate and accurate drug labeling, the inclusion of women and minority group members in clinical trials that establish the safety and effectiveness of drugs and biologics, seafood safety and inspection, medical uses of human tissue, unapproved and alternative uses of veterinary drugs, and improved food inspection authority.

Responding to the distress at the FDA, Congress has increased the agency's budget-- but not by nearly enough to remedy the problem. There is little reason to believe that the same Congress, if it should be persuaded to give tobacco regulation to the agency, would provide enough extra money to keep this new job from adding to the strains.

IV. Who Will Decide?

The FDA's incapacity to undertake the regulation of cigarettes is clear--so clear, in fact, that it raises the question of why some officials and anti-smoking activists are willing to take such serious risks with the country's general health and safety regulation in return for getting jurisdiction over tobacco.

There is also a larger, more important question: Why give basic decisions about tobacco and smoking to an appointed bureaucracy at all? Delegating authority to a regulatory agency is appropriate only

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when a broad national consensus exists about a policy problem and Congress has embodied that consensus in a law stating a general purpose and a general view of the issue. The regulatory agency then presumably uses its special expertise to implement the public's purpose.

Tobacco is not such a case. The practice of smoking cuts very close to fundamental questions about the relationship between individuals and society. It touches on issues of health, risk-taking, freedom, tolerance, and class bias. Opinions on these things are diverse and contradictory. Moreover, the expertise on which the FDA bases its claims in this area is scientifically dubious and ideologically tainted.

Thus smoking is one of those matters that should be dealt with by elected representatives accountable to the country's citizens. To be sure, many anti-smoking activists would rather push their policy agenda forward without the delay, inconvenience, and risk of a genuine democratic debate, because in a full debate the most rabid of these activists would almost surely lose. Such people should not be allowed to resort to the device of premature regulation and make the country bear its considerable costs.

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